

**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

FONTEM US, LLC,

Petitioner,

v.

No. 22-1076

U.S. FOOD AND DRUG ADMINISTRATION,

Respondent.

PUBLIC PROTECTIVE PETITION FOR REVIEW

Pursuant to 5 U.S.C. § 706, 21 U.S.C. § 387l(a), and Federal Rule of Appellate Procedure 15(a), Fontem US, LLC (Fontem) hereby petitions this Court for review of the Marketing Denial Order, dated April 8, 2022, issued by the United States Food and Drug Administration (FDA). The Marketing Denial Order denies Fontem's Premarket Tobacco Product Applications for certain of Fontem's electronic nicotine delivery system (ENDS) products. A copy of the Marketing Denial Order is attached to this petition as Exhibit A. Venue is proper in this Court pursuant to 28 U.S.C. § 2343 and 21 U.S.C. § 387l(a)(1).

Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), any tobacco product that was not commercially marketed as of, or which was modified after, February 15, 2007 must receive a marketing order from FDA prior to being

commercially marketed in the United States. 21 U.S.C. § 387j. In 2016, FDA enacted a rule that deemed ENDS products that contain nicotine derived from tobacco subject to regulation as “tobacco products.” 81 Fed. Reg. 28973 (May 10, 2016) (codified at 21 C.F.R. § 1143.1). Because certain ENDS products were already on the market prior to introduction of that rule, FDA provided staggered deadlines for meeting various FDCA requirements for tobacco products. 81 Fed. Reg. at 29009-15. If a new tobacco product does not comply with the premarket requirements of the Tobacco Control Act, FDA considers the product to be “adulterated.” 21 U.S.C. § 387b(6)(A); 21 U.S.C. §§ 331-33.

Fontem is petitioning for review of the Marketing Denial Order issued by FDA on April 8, 2022. *See Exhibit A.* In that order, FDA determined that Fontem’s reviewed ENDS products “lack[ed] sufficient evidence to demonstrate that permitting the marketing of the product” is “appropriate for the protection of the public health.” *Id.* at 1. The order violates the Administrative Procedure Act because it is contrary to law and arbitrary and capricious. 5 U.S.C. § 706. Fontem respectfully requests that the Court, on review, vacate or modify, in whole or in part, the foregoing order and also requests that the Court grant such further relief as may be deemed just and proper, including such relief as necessary to ensure that it may continue to market the products subject to the challenged order.

The Tobacco Control Act provides that judicial challenges to certain FDA orders with respect to tobacco products must be brought within 30 days. *See* 21 U.S.C. § 387l(a)(1). At the same time, FDA's regulations explicitly provide for a process of "supervisory review." 21 C.F.R. § 10.75(a) ("A decision of an FDA employee, other than the Commissioner, on a matter, is subject to review by the employee's supervisor"). Fontem hopes to resolve the issues addressed in the Marketing Denial Order through FDA's internal supervisory review process, and is in the early stages of pursuing such review. Out of an abundance of caution, however, due to the statutory deadline contained in the Tobacco Control Act, Fontem files this petition for review to protect its right to judicial review of the order.

Dated: May 6, 2022

Respectfully submitted,

/s/ Philip J. Perry

Philip J. Perry
Andrew D. Prins
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004
Tel.: (202) 637-2200
Fax: (202) 637-2201
philip.perry@lw.com

Counsel for Fontem US, LLC

**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

FONTEM US, LLC,

Petitioner,

v.

No. 22-1076

U.S. FOOD AND DRUG ADMINISTRATION,

Respondent.

RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, petitioner Fontem US, LLC (“Fontem”) respectfully submits the following corporate disclosure statement:

Fontem is a nongovernmental North Carolina limited liability corporation engaged in the manufacture of e-liquids for use in electronic nicotine delivery systems. Fontem’s sole member is ITG Brands Holdpartner LP, a North Carolina limited partnership. ITG Brands Holdpartner LP has two partners: ITG Brands Holdco LLC, a North Carolina limited liability corporation, and ITG Holdings USA Inc., a Delaware corporation. ITG Holdings USA Inc. is wholly owned by Imperial Brands PLC. Imperial Brands PLC (LSE:IMB) is a publicly traded United Kingdom public limited company. No publicly-held company has a 10% or greater ownership interest in Imperial Brands PLC.

Dated: May 6, 2022

Respectfully submitted,

/s/ Philip J. Perry

Philip J. Perry
Andrew D. Prins
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004
Tel.: (202) 637-2200
Fax: (202) 637-2201
philip.perry@lw.com

Counsel for Fontem US, LLC

EXHIBIT A

Marketing Denial Order, dated April 8, 2022

**NOT PUBLICLY AVAILABLE
MATERIAL DELETED**

CERTIFICATE OF SERVICE

Pursuant to Federal Rules of Appellate Procedure 15(c) and 25(d), I hereby certify that on May 6, 2022, a true and correct copy of the foregoing was served on the following by electronic mail and U.S. Postal Service first class mail, in addition to filing the Petition for Review electronically with the Clerk:

Robert Califf, Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
robert.califf@fda.hhs.gov

Mark Raza, Chief Counsel
Office of the Chief Counsel
United States Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 31
Silver Spring, MD 20993-0002
mark.raza@fda.hhs.gov

Michele Mital, Acting Director
Matthew R. Holman, Director, Office of Science
Barbara Banchero, Regulatory Health Project Manager
Center for Tobacco Products
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
michele.mital@fda.hhs.gov
matthew.holman@fda.hhs.gov
barbara.banchero@fda.hhs.gov

Daniel J. Barry, Acting General Counsel
United States Department of Health and Human Services
200 Independence Ave., SW, Room 713-F
Washington, DC 20201-0004
daniel.barry@hhs.gov

Xavier Becerra, Secretary
United States Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201-0004
xavier.becerra@hhs.gov

/s/ Philip J. Perry
Philip J. Perry
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004
Tel.: (202) 637-2200
Fax: (202) 637-2201
philip.perry@lw.com

Counsel for Fontem US, LLC